

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 02419
LITIGATION)	Docket No. 1:13-md-2419-RWZ
_____)	

This document relates to:

Handy v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14019-RWZ

Armetta v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14022-RWZ

Torbeck v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14023-RWZ

Kashi v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14026-RWZ

Bowman v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14028-RWZ

Dreisch v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14029-RWZ

Davis v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14033-RWZ

Farthing v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14036-RWZ

**BOX HILL DEFENDANTS’ STATEMENT OF UNDISPUTED MATERIAL FACTS IN
RELATION TO ITS MOTIONS FOR PARTIAL SUMMARY JUDGMENT**

The Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively “Defendants,” “Box Hill Defendants,” or “Box Hill”), by undersigned counsel, pursuant to Rule 56 of the Federal Rules of Civil Procedure and

LR, D. Mass. 56.1, respectfully submit this Statement of Undisputed Material Facts in relation to its contemporaneously filed Motions for Partial Summary Judgment.

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").¹

2. The tainted vials were limited to those in certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).² However, not every vial in each lot was contaminated.

3. Dr. Bhambhani administered MPA in vials from Lot # 05212012@68 and Lot # 06292012@26 while performing epidural steroid injection procedures.³

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.⁴

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.⁵ There were certainly more health care providers who purchased NECC's MPA prior to May 2012.

6. NECC was regulated and inspected by the U.S. Food and Drug Administration ("FDA").⁶ In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its

¹ Dreisch Complaint at 3, ¶ 1.

² Dreisch Complaint at 17, ¶ 51.

³ Dreisch Complaint at 37, ¶ 145.

⁴ See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

⁵ See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**

⁶ See FDA Warning Letter, attached as **Exhibit 3**.

position that “the Federal Food, Drug, and Cosmetic Act (“FDCA”) establishe[d] agency jurisdiction” over NECC.⁷

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, as well as an inspection by Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.⁸

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.⁹

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.¹⁰

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection

⁷ *Id.*

⁸ See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

⁹ Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

¹⁰ See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

with the 2012 nationwide fungal meningitis outbreak.¹¹ As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.¹²

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.¹³

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.¹⁴

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.¹⁵ Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.¹⁶

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.¹⁷

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.¹⁸

¹¹ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

¹² Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

¹³ See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

¹⁴ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

¹⁵ See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

¹⁶ See *id.*

¹⁷ See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

¹⁸ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Gregory K. Kirby, hereby certify that a copy of the foregoing document, filed through the CM/ECF system will be accessible to those attorneys who are registered with the Court's electronic filing system and Notice of Electronic filing (NEF), including the attorneys representing the plaintiffs in the above-referenced individual cases, and will be sent to these parties by operation of the CM/ECF system on September 18, 2017.

/s/ Gregory K. Kirby

Gregory K. Kirby